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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,355	03/03/2004	Bruno Pfeiffer	SERVIER 396 PCT	5116

25666 7590 04/10/2007
THE FIRM OF HUESCHEN AND SAGE
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KALAMAZOO, MI 49007

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/792,355	Applicant(s) PFEIFFER ET AL.	
	Examiner Robert Shiao	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application: FRANCE 00/08793 with a filing date 07/06/2000; and FRANCE 00/08973 with a filing date 07/06/2000. The foreign priority document FRANCE 00/08793 has been filed to the Office on February 12, 2007. However, the foreign priority document FRANCE 00/08973 has not been filed to the Office. Applicants are requested to file the foreign priority document to the Office.
2. Amendment of claim 23 in the amendment filed on February 12, 2007, is acknowledged. Claims 14-26 are pending in the application.

Responses to Arguments

3. Applicant's arguments regarding the rejection of claims 25-26 over Guez et al. US 6,653,336 under 35 U.S.C. 102(e) filed on February 12, 2007, have been fully considered and they are not persuasive. It is noted that Guez et al. disclose the same solid pharmaceutical composition (i.e., tablet) comprising a diuretic indapamide. The rejection of claims of 25-26 over Guez et al. '336 under 35 U.S.C. 102(e), is maintained.
4. Applicant's arguments regarding the provisional rejection of claims 23 and 25-26 under the obvious-type double patenting over Pfeiffer et al. co-pending application No. 11/052,489 in view of Brittain's publication filed on February 12, 2007, have been fully considered and they are not persuasive. Applicants are requested to disclose the instant pharmaceutical composition does not render obviousness of Pfeiffer

et al. in terms of mechanic benefits. A side-by-side comparison between the instant pharmaceutical composition and Pfeiffer et al. after the processes of preparation is needed to overcome the obviousness. The provisional rejection of claims 23 and 25-26 under the obvious-type double patenting is maintained, and applicants are requested to file a terminal disclaimer to overcome the rejection.

5. Applicant's arguments regarding the rejection of claims 23 and 25-26 under 35 U.S.C. 112, first paragraph filed on February 12, 2007, have been fully considered and they are not persuasive. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, the instant α crystalline form, after mixing, grinding, compressing would be transformed into a thermodynamically stable form(s). Applicants are requested to disclose that the instant pharmaceutical composition comprising α crystalline form is stable, and not changing to another form, after the processes of pharmaceutical preparation.

6. Applicant's arguments regarding the rejection of claims 14, 23 and 25-26 under 35 U.S.C. 102(b) or 103(a) over Guez et al. WO 99/25374 filed on February 12, 2007 have been fully considered and they are not persuasive. Guez et al. do disclose the instant same solid compound (i.e., in a solid tablet composition) but is silent on the instant X-ray diffraction data. It is noted that the crystalline form of a compound is an innate nature of a solid compound. Applicants are requested to disclose the instant α crystalline form of compound and its pharmaceutical composition does not render obviousness of Guez et al. in terms of superior properties and

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mechanic benefits. The rejection of claims 23 and 25-26 under 35 U.S.C. 102 (b), or the rejection of claims 14, 23 and 25-26 under 35 U.S.C. 103(a) over Guez et al. is maintained.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

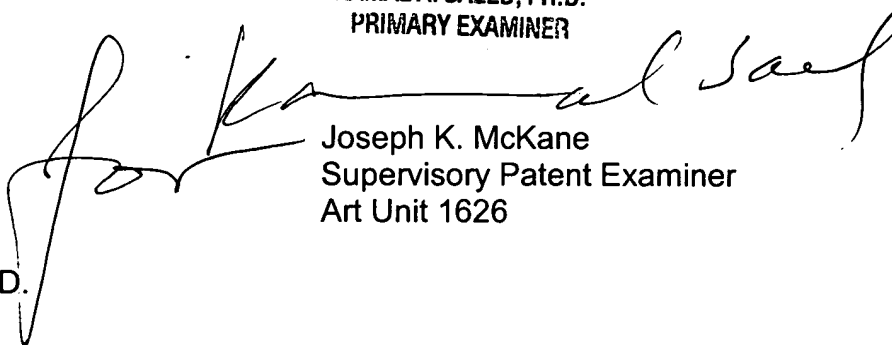
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from

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the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

Rs

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

March 29, 2006